UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,529	09/22/2003	Marc E. Surette	3009-P02297US2	9936

110 7590 11/04/2004

DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,529	SURETTE, MARC E.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09222003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 14 is objected to because of the following informalities: The claim does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, line 2, "said single dose" lack sufficient antecedent basis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US 4999380) in view of Klor et al. (US 5886037) and/or Loria (WO 93/21774).

Applicant claims a method for treating hypertriglyceridemia, the method comprising administering an effective amount of a composition comprising fatty acyl compounds, wherein the fatty acyl compounds have a polyunstaruated fatty acid content of at least 65%; and includes about 10 – 35% linoleic acid, about 5 – 50% gamma linolenic acid, about 15 – 60% alpha linolenic acid, and about 15 – 55% stearidonic acid; and optionally in combination with a therapeutic agent selected from an antilipemic, antioxidant or antidiabetic agent. The composition is administered in an amount that delivers about 0.04 – 0.35 grams of fatty acyl compounds per kilogram of patient body weight per day. The composition is administered orally and in a single dose.

Berger teaches a method for treating hyperlipidemia (or hypretriglyceridemia) (col.1 line 44-64), comprising administering a composition of blackcurrant seed oil, which comprises 45% linoleic acid, 17% gamma linolenic acid, 13% alpha linolenic acid and 3.5% stearidonic acid (col.2 line 45-60). The composition is administered orally in a single dose of 1 – 25g (claims).

Berger does not teach the method wherein the composition comprises the exact percents of fatty acids, or wherein the dose is administered as claimed. However, the disclosed percent of fatty acids do overlap or are close to the claimed amounts. In addition, Klor and Loria teach methods for treating increased serum lipids (hypertriglyceridemia) by administering varying dosages of compositions comprising varying percents of fatty acyl compounds. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the effective amounts of fatty acids and dosages of Berger as a matter of routine experimentation,

as evidenced by Klor and/or Loria. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Berger, Klor and/or Loria, to optimize the dosages and percentages of fatty acyl compounds of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

6. Claims 8 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger in view of Klor and/or Loria, and further in view of Coupland (US 6340485 B1).

Applicant claims a method for treating hypertriglyceridemia, the method comprising administering an effective amount of a composition comprising fatty acyl compounds, wherein the fatty acyl compounds have a polyunstaruated fatty acid content of at least 65%; and includes about 10 – 35% linoleic acid, about 5 – 50% gamma linolenic acid, about 15 – 60% alpha linolenic acid, and about 15 – 55% stearidonic acid; and optionally in combination with a therapeutic agent selected from an antilipemic, antioxidant or antidiabetic agent. The composition is administered in an amount that delivers about 0.04 – 0.35 grams of fatty acyl compounds per kilogram of patient body weight per day. The composition is administered orally and in a single dose. The single dose comprises Echium oil, the composition delivers about 15 g Echium oil per day, and the polyunsaturated fraction is concentrated.

Berger teaches a method for treating hyperlipidemia (or hypretriglyceridemia) (col.1 line 44-64), comprising administering a composition of blackcurrant seed oil, which comprises 45% linoleic acid, 17% gamma linolenic acid, 13% alpha linolenic acid and 3.5% stearidonic acid (col.2 line 45-60). The composition is administered orally in a single dose of 1 – 25g (claims).

Berger does not teach the method wherein the composition comprises the exact percents of fatty acids, or wherein the dose is administered as claimed. However, the disclosed percent of fatty acids do overlap or are close to the claimed amounts. In addition, Klor and Loria teach methods for treating increased serum lipids (hypertriglyceridemia) by administering varying dosages of compositions comprising varying percents of fatty acyl compounds. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the effective amounts of fatty acids and dosages of Berger as a matter of routine experimentation, as evidenced by Klor and/or Loria. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Berger, Klor and/or Loria, to optimize the dosages and percentages of fatty acyl compounds of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

Berger does not teach the method wherein the fatty acid composition comprises Echium oil. Howevever, Coupland teaches Echium oil contains the same fatty acids in similar and/or overlapping amounts to that of blackcurrant seed oil. Specifically, Coupland teaches that Echium oil comprises about 10 – 20% linoleic acid, about 5 – 12% gamma linolenic acid, about 28 – 50% alpha linolenic acid, and about 5 – 20% stearidonic acid (table 2). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use Echium oil in the methods of Berger, since it was known to contain the same fatty acids at similar amounts to the blackcurrant seed oil of Berger, as evidenced by Coupland. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Coupland to use Echium oil in the methods of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

Although the references do not teach administering 15 g Echium oil per day, or wherein the fatty acid fraction is concentrated, it would have been obvious to one of ordinary skill to optimize the dose and fatty acid content in accordance with the methods of Berger as a matter of standard practices and experimentation. As such, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by standard practice to optimize the concentration of Echium oil and dosages of Coupland and use the obtained oil in the methods of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

7. Claims 8 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klor in view of Loria and further in of Berger.

Applicant claims a method for treating hypertriglyceridemia, the method comprising administering an effective amount of a composition comprising fatty acyl compounds, wherein the fatty acyl compounds have a polyunstaruated fatty acid content of at least 65%; and includes about 10 – 35% linoleic acid, about 5 – 50% gamma linolenic acid, about 15 – 60% alpha linolenic acid, and about 15 – 55% stearidonic acid; and optionally in combination with a therapeutic agent selected from an antilipemic, antioxidant or antidiabetic agent. The composition is administered in an amount that delivers about 0.04 – 0.35 grams of fatty acyl compounds per kilogram of patient body weight per day. The composition is administered orally and in a single dose.

Klor teaches a method for treating hypertriglyceridemia (col.2 line 1-3,21-29), comprising administering a composition comprising fatty acyl compounds at about 55 – 95% (abstract); and includes about 0 – 30% linoleic acid, gamma linolenic acid, (col.3 line 7-15,

abstract), about 55 – 95% stearidonic acid (col.2 line 63-68, abstract), and antioxidants (col.3 line 54). The composition is administered orally in single doses, which may contain 9 – 112 g fatty acid sources per day (col.4 line 23-27, 52-64).

Klor does not teach the composition further comprising alpha linolenic acid. However, Loria teaches that alpha linolenic acid is effective for treating excess lipids (or hypertriglyceridemia) (p.3) and that addition of alpha linolenic acid to other fatty acid compositions results in lowering of serum cholesterol (or reduces serum lipids) (p.4). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to include alpha linolenic acid in the composition of Klor because of its disclosed advantage of reducing serum lipids (or treating lypertriglyceridemia). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Loria to include alpha linolenic acid in the composition and methods of Klor with a reasonable expectation for successfully treating hypertriglyceridemia.

Although the references do not teach the method wherein the composition comprises the exact percents of fatty acids, or wherein the dose is administered as claimed, the disclosed percent of fatty acids do overlap or are close to the claimed amounts. In addition, Berger teaches methods for treating hypertriglyceridemia by administering varying dosages of compositions comprising varying percents of fatty acyl compounds. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the effective amounts of fatty acids and dosages of Klor and Loria as a matter of routine experimentation, as evidenced by Berger. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Klor, Loria, and Berger to optimize the dosages and percentages of fatty

acyl compounds of Klor and Loria with a reasonable expectation for successfully treating hypertriglyceridemia.

8. Claims 8 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klor in view of Loria and Berger, and further in view of Coupland.

Applicant claims a method for treating hypertriglyceridemia, the method comprising administering an effective amount of a composition comprising fatty acyl compounds, wherein the fatty acyl compounds have a polyunstaruated fatty acid content of at least 65%; and includes about 10 – 35% linoleic acid, about 5 – 50% gamma linolenic acid, about 15 – 60% alpha linolenic acid, and about 15 – 55% stearidonic acid; and optionally in combination with a therapeutic agent selected from an antilipemic, antioxidant or antidiabetic agent. The composition is administered in an amount that delivers about 0.04 – 0.35 grams of fatty acyl compounds per kilogram of patient body weight per day. The composition is administered orally and in a single dose. The single dose comprises Echium oil, the composition delivers about 15 g Echium oil per day, and the polyunsaturated fraction is concentrated.

Klor teaches a method for treating hypertriglyceridemia (col.2 line 1-3,21-29), comprising administering a composition comprising fatty acyl compounds at about 55 – 95% (abstract); and includes about 0 – 30% linoleic acid, gamma linolenic acid, (col.3 line 7-15, abstract), about 55 – 95% stearidonic acid (col.2 line 63-68, abstract), and antioxidants (col.3 line 54). The composition is administered orally in single doses, which may contain 9 – 112 g fatty acid sources per day (col.4 line 23-27, 52-64).

Klor does not teach the composition further comprising alpha linolenic acid. However, Loria teaches that alpha linolenic acid is effective for treating excess lipids (or hypertriglyceridemia) (p.3) and that addition of alpha linolenic acid to other fatty acid compositions results in lowering of serum cholesterol (or reduces serum lipids) (p.4). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to include alpha linolenic acid in the composition of Klor because of its disclosed advantage of reducing serum lipids (or treating lypertriglyceridemia). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Loria to include alpha linolenic acid in the composition and methods of Klor with a reasonable expectation for successfully treating hypertriglyceridemia.

Although the references do not teach the method wherein the composition comprises the exact percents of fatty acids, or wherein the dose is administered as claimed, the disclosed percent of fatty acids do overlap or are close to the claimed amounts. In addition, Berger teaches methods for treating hypertriglyceridemia by administering varying dosages of compositions comprising varying percents of fatty acyl compounds. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the effective amounts of fatty acids and dosages of Klor and Loria as a matter of routine experimentation, as evidenced by Berger. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Klor, Loria, and Berger to optimize the dosages and percentages of fatty acyl compounds of Klor and Loria with a reasonable expectation for successfully treating hypertriglyceridemia.

Klor and Loria do not teach the method wherein the fatty acid composition comprises Echium oil. Howevever, Coupland teaches Echium oil contains the same fatty acids in similar and/or overlapping amounts to that of the composition obtained by the combined teachings of Klor and Loria. Specifically, Coupland teaches that Echium oil comprises about 10 – 20% linoleic acid, about 5 – 12% gamma linolenic acid, about 28 – 50% alpha linolenic acid, and about 5 – 20% stearidonic acid (table 2). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use Echium oil in the methods of Klor and Loria, since it was known to contain the same fatty acids at similar amounts to the composition obtained by the combined teachings, as evidenced by Coupland. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Coupland to use Echium oil in the methods of Klor and Loria with a reasonable expectation for successfully treating hypertriglyceridemia.

Although the references do not teach administering 15 g Echium oil per day, or wherein the fatty acid fraction is concentrated, one of ordinary skill in the art would have been motivated to optimize the dose and fatty acid content in accordance with the methods of Klor and Loria as a matter of standard practices and experimentation. As such, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by standard practice to optimize the concentration of Echium oil and dosages of Coupland and use the obtained oil in the methods of Klor and Loria with a reasonable expectation for successfully treating hypertriglyceridemia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
October 13, 2004
AU 1651